

REMARKS

The title has been changed to more particularly reflect the claimed subject matter. The amendment to the title does not add new matter.

Claims 1-21 are canceled without prejudice to, or disclaimer of, the subject matter contained therein. Applicants maintain that the cancellation of a claim makes no admission as to its patentability and reserve the right to pursue the subject matter of the canceled claims in this or any other patent application.

New Claims 22-29 are added. New Claim 22 is supported by the specification, for example, at page 4, lines 7 to 21, and page 9, line 7 to page 11, line 25. New Claim 23 is supported by the specification, for example, at page 6, lines 5 to 10. New Claim 24 is supported by the specification, for example, at page 10, lines 1 to 10. New Claim 25 is supported by the specification, for example, at page 6, line 21 to page 7, line 3 and page 8, lines 11 to 18. New Claim 26 is supported by the specification, for example, at page 9, line 7 to page 11, line 25. New Claim 27 is supported by the specification, for example, at page 10, lines 14 to 17. New Claims 28 and 29 are supported by the specification, for example, at page 11, lines 5 to 8. The new claims do not add new matter.

Upon entry of the amendment, Claims 22-29 are pending.

Information Disclosure Statement

Applicants submit herewith a new IDS providing including the previously cited reference DE 3442961, accompanied by an English abstract. Also provided in the new IDS are the publication by Bruhl and the publication by Casadebaig-Lafon, which were previously submitted in an IDS mailed October 2, 2006. These two references were crossed out as not considered by the Examiner. However, the abstract and summary, respectively, of these articles are in English, and, therefore are appropriate for consideration. Accordingly, Applicants respectfully request consideration of the English abstract and summary, respectively, of these documents.

Objection to the Specification

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The Office Action objects to the title as not descriptive. Applicants have amended the title herein to incorporate language as suggested in the Office Action. In view of the amendment to the title, Applicants respectfully request removal of this objection.

Objection to the Claims

The Office Action objects to the claims as containing informalities of genus and species names being underlined instead of italicized. Applicants have canceled the objected-to claims. Applicants' new claims contain genus and species names italicized. Accordingly, Applicants submit that the new claims are not objectionable as to the listing of genus and species names.

Rejection under 35 U.S.C. §112, Second Paragraph

Claims 1, 2, 4 and 5 were rejected under 35 U.S.C. §112, second paragraph as being indefinite. The Office Action objected to the phrases "for oral use" and "extracts thereof" of Claim 1, the Markush group of Claim 2 in view of Claim 1, and the phrase "food for hair growth" in Claims 4 and 5.

Claims 1, 2, 4 and 5 are canceled herein. Accordingly, the rejection as to these claims is moot.

Applicants have added new Claims 22-29. The rejections as they may apply to these claims is addressed below.

Regarding "for oral use," the new claims do not recite the phrase "for oral use." Thus, this ground for rejection is moot.

Claim 22 recites "at least one plant selected from the genus *Orthosiphon* in the family *Laminaceae*, or extract thereof," and Claims 25 recites "wherein said extract is obtained by extracting with a solvent selected from the group consisting of water, C₁₋₃ alcohol, and a mixture thereof." Applicants submit that the term "extract" as used in the claims, is clear and definite in view of the knowledge in the art and the teachings of the specification. The Office Action states:

In the case of "and extracts thereof", what type of extracts is Applicant claiming? Is Applicant claiming aqueous or organic extracts or is Applicant claiming specific active compounds? The lack of clarity renders the claims indefinite since

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the resulting claims do not clearly set forth the metes and bounds of the patent protection desired. *Office Action* at page 4.

Applicants' specification teaches and exemplifies preparation of extracts, which can be, e.g., aqueous or alcohol extracts of the plant material:

Extracts of the plants can be obtained by chopping the raw or dried plant and subjecting the chopped plant to extraction with a suitable solvent, which is preferably water, a lower alcohol or a mixture thereof.

Lower alcohols usable for extraction include C₁₋₃ alcohols, such as methanol, ethanol, etc., among which ethanol is most preferable. These alcohols may also be hydrous alcohol (water content: 0.1 to 99.9%).

The extraction can be performed by a batch process, percolation process, reflux process or other known processes. The proportion of the extraction solvent is not limited, and is suitably 2 to 1000 parts relative to 1 part of the chopped raw or dried plant. The extraction can be carried out at room temperature or with heating.

Preferably, the extraction is performed at a temperature range of room temperature to about 80°C for about 1 hour to about 10 hours while stirring under mild conditions. The extraction may also be carried out by adding the solvent dropwise to a cylinder filled with the chopped raw or dried plant.

(i) Preparation of Extract

One hundred grams of a dried whole plant of cat's whiskers, simpleleaf chastetree or lilac chastetree was chopped. Ethanol (2000 ml) was added, and the resulting mixture was heated to 70°C for 2 hours to perform extraction. After filtration, 2000 ml of ethanol was further added to the residue, and extraction was carried out for 2 hours more. The filtrates obtained by the two extraction steps were combined, concentrated under reduced pressure, and freeze-dried to obtain an extract. *Specification* at page 6, line 21, through page 7, line 16 and page 12, lines 8-17.

In view of these teachings in the specification, one skilled in the art would understand the meaning of the term "extracts" as recited in the claims. Accordingly, Applicants submit that the claims are not indefinite by virtue of reciting the term "extracts."

Regarding the rejection as to the Markush group recited in Claim 2, this claim is no longer pending and no new claim recites the objected to Markush group as it was recited in Claim 2. New Claim 23 recites a Markush group, but Applicants submit that the language of

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Claim 23 is in proper form and its scope is clear and definite. Accordingly, Applicants submit that the claims should no longer be subject to this ground of rejection.

Regarding the rejection of the phrase "food for hair growth," Claims 4 and 5 are canceled herein, and, therefore, this rejection is moot. New Claims 22-29 do not recite "food for hair growth," and, as such, do not contain the objected-to phrase. New Claim 26 does recite a food form, as: "a food form selected from the group consisting of soft drink, juice, tea, powdered juice, powdered soup, cookie, biscuit, cereal, chewing gum, candy, tablet, wafer, rice cracker." The food forms recited in Claim 26 are specific, and, thus, will be clear and definite to those skilled in the art. Accordingly, Applicants submit that the claims should no longer be subject to this ground of rejection.

Rejection under 35 U.S.C. §102(b)

Claims 1, 2, 4 and 5 were rejected under 35 U.S.C. §102(b) as being anticipated by Nakaguchi et al. (JP 2001-031528).

Claims 1, 2, 4 and 5 are canceled herein. Thus, the rejection as to these claims is moot. The rejection as it applies to the subject matter of the new claims is discussed below.

New Claims

New Claims 22 is directed to an edible composition comprising: (a) an amount of at least one plant selected from the genus *Orthosiphon* in the family *Laminaceae*, or extract thereof, effective to stimulate hair growth upon ingestion; and (b) at least one edible ingredient added thereto. New Claims 23-29 depend from Claim 22 and are directed to particular embodiments including, *inter alia*: an edible composition comprising 0.1 to 100 g, calculated as dried plant, of the plant or extract thereof; an edible composition in a food form selected from the group consisting of soft drink, juice, tea, powdered juice, powdered soup, cookie, biscuit, cereal, chewing gum, candy, tablet, wafer, rice cracker; an edible composition in a form selected from the group consisting of tablets, powder, granules, capsules and chewable tablets; an edible composition in a form selected from the group consisting of a solid mass, syrup, powder and jelly; and an edible composition in liquid form.

The Reference

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Nakaguchi discloses:

[0031] In addition, said hair restorer constituent can be used as cosmetics, quasi drugs, or drugs, for example, can be used as a hair tonic, a hair cream, and hair treatment.

Nakaguchi does not Anticipate New Claims 22-29

Applicants submit that Nakaguchi does not anticipate Claims 22 or any claim dependent therefrom because Nakaguchi does not disclose a composition containing the recited plant or extract and at least one edible ingredient, nor does Nakaguchi disclose an edible composition comprising an amount of the recited plant or extract thereof that is effective to stimulate hair growth upon ingestion. The dependent claims are further novel over the reference because the reference does not teach or suggest the various embodiments recited therein.

The Office Action states:

Nakaguchi teaches a hair growth stimulant comprising *Orthosiphon aristatus* Bold., which may be used as a cosmetic, quasi drug or drug or may be used as a hair tonic, hair cream or hair treatment, which reads on food for hair growth. *Office Action* at page 5.

As Applicants have excerpted above, Nakaguchi actually discloses cosmetics, quasi drugs, or drugs, for example, can be used as a hair tonic, a hair cream, and hair treatment. Thus, Nakaguchi exemplifies that the cosmetics, quasi drugs or drugs can be in the form of “a hair tonic, a hair cream, or hair treatment,” all of which are topical compositions, which do not necessarily read on food for hair growth. There is no disclosure of Nakaguchi’s “hair restorer” in an edible composition form, as is recited in Applicants’ claims. Nakaguchi’s teaching of “cosmetics, quasi drugs, or drugs” does not inherently read on edible compositions because the only exemplification provided by Nakaguchi is of the topical compositions “a hair tonic, a hair cream, or hair treatment.” To establish inherency, the evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. None of “a hair tonic, a hair cream, or hair treatment” taught by Nakaguchi are necessarily edible compositions comprising at least one edible ingredient in addition to the recited plant or extract. Accordingly, Nakaguchi does not anticipate the claims.

Even if Nakaguchi had disclosed an edible composition containing Nakaguchi’s “hair restorer” and at least one edible ingredient in addition to the recited plant or extract, Nakaguchi

does not disclose an amount of at least one plant selected from the genus *Orthosiphon* in the family *Laminaceae*, or extract thereof, effective to stimulate hair growth upon ingestion. Applicants have discovered that the recited plant or extract thereof can stimulate hair growth upon ingestion, and Applicants have provided compositions containing an amount of the recited plant or extract thereof effective to stimulate hair growth upon ingestion. Nakaguchi does not disclose any amount of Nakaguchi's "hair restorer" that can be effective to stimulate hair growth upon ingestion. Furthermore, none of Nakaguchi's teachings inherently disclose Nakaguchi's "hair restorer" in an edible form, and containing an amount of the plant or extract recited in Applicants' claims that can be effective to stimulate hair growth upon ingestion. As such, Nakaguchi further cannot anticipate the claimed compositions. Moreover, Nakaguchi only contemplated topical application of Nakaguchi's "hair restorer," and Nakaguchi provides no guidance whatsoever on whether or not such topical formulations could be modified to be effective to stimulate hair growth upon ingestion. Accordingly, it would not have been obvious to modify Nakaguchi's teachings to arrived at the claimed compositions. In view of the above, Applicants submit that the claims are patentable over Nakaguchi.

The Dependent Claims are further Novel over Nakaguchi

New Claims 23-29 depend from Claim 22 and are directed to particular embodiments including, *inter alia*: an edible composition comprising 0.1 to 100 g, calculated as dried plant, of the plant or extract thereof; an edible composition in a food form selected from the group consisting of soft drink, juice, tea, powdered juice, powdered soup, cookie, biscuit, cereal, chewing gum, candy, tablet, wafer, rice cracker; an edible composition in a form selected from the group consisting of tablets, powder, granules, capsules and chewable tablets; an edible composition in a form selected from the group consisting of a solid mass, syrup, powder and jelly; and an edible composition in liquid form.

As discussed above, Nakaguchi does not disclose a composition containing the recited plant or extract and at least one edible ingredient, or an edible composition comprising an amount of the recited plant or extract thereof that is effective to stimulate hair growth upon ingestion. In addition, Nakaguchi is silent as to quantities of the plant or extract present in an edible composition, or food or other particular edible forms in which the edible compositions can be formulated, as recited in various dependent claims. As such, Nakaguchi cannot anticipate

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these claims. Furthermore, because Nakaguchi does not contemplate that Nakaguchi's topical formulations could be modified to be effective to stimulate hair growth upon ingestion, it would not have been obvious to modify Nakaguchi's teachings to arrive at the compositions as recited in various dependent claims. As such, Applicants submit that the dependent claims are further patentable over Nakaguchi.

CONCLUSION

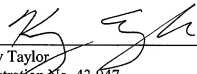
In view of the above, Applicants respectfully maintain that claims are patentable and request that they be passed to issue. Applicants invite the Examiner to call the undersigned if any remaining issues might be resolved by telephone.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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